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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,753	01/02/2002	Stanley Hazen	26473/04177	9142
24024 7590 02/21/2007 CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			EXAMINER SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/039,753

Applicant(s)

HAZEN ET AL.

Examiner

David A. Saunders, PhD

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 03 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: ... (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): SEE ATTACHED.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 1-5, 7-10, 23, 25, 28, 31, 32 and 34-39.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 26, 29 and 33.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: SEE ATTACHED.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

**ISSUES OF RECORD THAT WOULD BE OVERCOME UPON ENTRY OF AMENDMENT OF 1/3/07**

1) the objection to claims 2,28,32,35,38 under 37 CFR ( c).

2) the rejection of claims 1-5, 7-10, 23, 25-26, 28-29, 31-33, 35-39 under 112, 2<sup>nd</sup>. The term "risk of having" can be properly interpreted as meaning that a subject with high levels of MPO has a high probability (risk) of having atherosclerotic cardiovascular disease.

3) the rejection of claims 23,37,39 under 102 (a) over Zhang et al. Applicant's urgings regarding earlier filed support for the claimed invention, based upon both provisional applications, are convincing of patentability over Zhang et al

**ISSUES THAT WOULD BE REMAINING UPON ENTRY OF AMENDMENT OF 1/3/07**

1) the rejection of claims 26 and 29 under 102 (a) over Zhang et al. With respect to the "control subjects" recited in claim 26, such generic recitation is not supported by the '432 application. Applicant's urgings filed on 1/3/07, with respect to the controls, are set forth at page 8. Therein the statement that "Claims 23, 29, 37, and 39 recite control subjects that are the same as the control subjects of claim 26" is erroneous, since claims 23 and 37 recite "control subjects diagnosed as not having the disease". Thus claims 23 and 37 are supported by the earlier filed provisional applications, while claim 26 is not.

2) a rejection of claim 33 under 102 (a) over Zhang et al. While this has not been previously stated, it is considered that Zhang et al's teachings of measuring MPO mass per neutrophils would anticipate "neutrophils" now recited in claim 33, or would anticipate "blood leukocytes" previously recited in claim 33. While the provisional applications support the recitation of "neutrophils or monocytes", it is to be noted that, as stated supra for claim 26, the "control subjects" generically recited in claim 33 are not supported by the '432 application. Since applicant has submitted an undue number of

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after FINAL responses, each presenting an undue number of independent claims, the examiner shall not give applicant the privilege of responding to a new non-final rejection on this point, especially since the issue raised regarding claim 33 pertains to the same issue that remains in the previously stated rejection of claim 26 and dependent claim 29.

## CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/16/07 DAS

  
DAVID A. SAUNDERS  
PRIMARY EXAMINER